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| 09/773,976 | 01/31/2001 | Paul Sun | 87165-9051 | 6280 |

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MICHAEL BEST & FRIEDRICH, LLP
ONE SOUTH PINCKNEY STREET
P O BOX 1806
MADISON, WI 53701

EXAMINER

FOX, DAVID T

| ART UNIT | PAPER NUMBER |
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1638

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DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/73,976Applicant(s)
Sun et alExaminer
FOXGroup Art Unit
1635

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE - 3 - MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 3/5/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-9 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-9 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).
- *Certified copies not received: _____.

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants' amendments of 5 March 2003 and accompanying arguments have obviated all rejections under 35 USC 112, second paragraph, except as indicated below; and have obviated all rejections applied to claim 10.

Claim 9 (newly amended) remains indefinite in its recitation of "crossing only the male fertile plants of step (c)", as it is unclear what is intended. Replacement of "crossing only" with --selfing--, as recited on page 6 of the specification, lines 20-22, would obviate this rejection.

Claims 1-9 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated on pages 5-9 of the last Office action for claims 1-10. However, the portion of the rejection directed to the incorporation of male sterility into various alfalfa breeding lines is no longer maintained, in view of Applicants' arguments and given further consideration by the Examiner, as stated below.

Claims 1-4 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention with regard to a biological deposit, as stated on pages 9-11 of the last Office action.

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Claims 1-4 remain rejected under 35 U.S.C. 102(b) as being anticipated by Northrup et al (1972, Seed Scoop 19:6), as stated on pages 11-12 of the last Office action.

Claims 2-4 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over each of Northrup et al and Thompson et al (1974), as stated on pages 12-13 of the last Office action.

Claims 5-6 and 9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al, as stated for claims 5-6 and 9-10 on pages 14-16 of the last Office action.

Claims 5-7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al in view of Viands et al, as stated on pages 16-17 of the last Office action.

Claims 5 and 8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al in view of Rotili et al, further in view of Vos et al, as stated on pages 17-18 of the last Office action.

No claim is allowed.

Applicants' arguments filed 5 March 2003, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicants urge that the enablement rejection is improper, given the recognition by those skilled in the art that the deposited alfalfa cultivar was produced by crossing clonal parental breeding lines rather than heterogeneous synthetic varieties, as also urged by the Sun declaration of 5 March 2003 (which is a duplicate of the Sun declaration of 16 September 2002). Applicants urge that methods of incorporating male sterility into a variety of alfalfa lines are well-known.

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Applicants further urge that the determination of percent hybridity is not unpredictable, given its known calculation in the art as demonstrated by Sun et al cited by the Examiner.

The Examiner maintains that Applicants' assertion that their parental lines would not have been recognized by the skilled artisan as synthetic varieties is not persuasive, given the fact that at least one of Applicants' parental lines, namely 'Thor', is clearly a synthetic variety (see, e.g., Northrup et al, 1972, Seed Scoop 19:6, column three, first paragraph of "Thor Alfalfa"). If individual selections from the original 'Thor' synthetic variety were used and further bred by Applicants, they were not indicated in the instant specification. Such a deficiency renders those skilled in the art unable to make and/or use the invention. Furthermore, in the absence of any genetic or pedigree information about the other parental lines of the claimed deposited variety, and given the knowledge in the art that synthetic varieties are widely employed in alfalfa breeding, it is unclear that the other parental lines were not synthetics as well.

Regarding the incorporation of male sterility, the Examiner notes that the Sun et al (U.S. 4,045,912) broadly claims the incorporation of male sterility into any alfalfa cultivar, thereby demonstrating the ability of the skilled artisan to do so. Accordingly, this portion of the enablement rejection has been withdrawn.

Regarding the determination of hybridity, the Examiner notes that general methods for determining hybridity using a morphological marker, as was done by Sun et al (U.S. 4,045,912) who apparently used seed yield as a marker for hybridity, have been enabled. However, no guidance is provided for molecular marker-based methods for determining hybridity in alfalfa, as

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claimed in claims 7-8, given the unpredictability inherent in the process as set forth in the first Office action, and given the lack of disclosure of any genetic or molecular marker in alfalfa in the instant application.

Regarding the deposit of the claimed alfalfa variety, the Examiner notes that Applicants have stated on page 3 of the specification that the variety was deposited under the terms of the Budapest Treaty. However, such a statement alone does not satisfy all of the criteria set forth in 37 CFR 1.801-1.809. A statement over the signature of Applicants' representative that all restrictions upon public availability of the seed will be irrevocably removed upon granting of the patent is also required. Furthermore, given the involvement of many synthetic varieties in the pedigree of the claimed alfalfa variety, it is unclear whether 2500 seeds is sufficient to represent the variety, as stated in the last Office action.

Applicants urge that the rejections of claims 1-4 under 35 USC 102 are improper, given the Examiner's mischaracterization of the deposited variety and its parentage. The Examiner maintains that at least one synthetic variety, namely 'Thor', was involved in the production of the claimed variety, which is therefore also a synthetic variety. Since claim 1 is drawn to a single seed, it reads on a seed of 'Thor' which would be included in the collection of individuals that comprise the claimed variety.

Furthermore, since Applicants have defined "derived from" as encompassing plants grown from seed which has been produced by plants of the claimed variety, i.e. progeny plants produced by crossing the claimed variety with undisclosed crossing partners, claims 2-4 clearly read on

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prior art alfalfa plants which would segregate in the population of progeny plants, and parts thereof. Amendment of claim 2 to replace "derived" with --grown-- may help to address this particular issue.

Applicants urge that the rejections under 35 USC 103 are improper, given the failure of the primary reference to teach or suggest the use of a 4:1 planting ratio to obtain greater than 75% hybridity, and the failure of the secondary references to cure the deficiencies of the primary reference.

The Examiner maintains that Applicants have not demonstrated any advantage in increasing the planting ratio to 4:1, since Sun et al obtained greater than 75% hybridity without increasing it over 3:1. Thus, the increase of the planting ratio appears to have been the mere optimization of process parameters. See In re Kuhle, 188 USPQ 7, (CCPA 1975), which teaches that a feature which solves no stated problem and which presents no unexpected results would have been an obvious matter of choice.

In addition, Applicants' putative unexpected results, namely the production of greater than 75% hybridity following the use of a 4:1 planting ratio, depends upon the use of a particular alfalfa variety. In contrast, the claims are broadly drawn to any male sterile and male fertile alfalfa variety. See In re Lindner, 173 USPQ 356 (CCPA 1972) and In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

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Since the primary reference is not deficient, the secondary references do not need to cure any deficiency.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 29, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180 1638

